Remarks

Claims 52-69 are presented for the Examiner's review and consideration. Claim 52 has been amended. Applicant believes the claim amendment and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102 Claim Rejections

Claims 52, 55, and 64-66 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,718,159 to Thompson ("Thompson").

The Office Action asserts that Figs. 16 and 17 of Thompson show a plurality of stent performs interlaced to form a stent. The Office Action also submits that Thompson discloses the core strands are made of metal and can be shape memory alloy. The Examiner further stated that Thompson discloses the strands are coated with therapeutic agent.

However, the Office Action failed to show that Thompson discloses a strand including an outer sheath disposed about its contact surface or caps disposed on the ends of the outer sheath thereby encapsulating the strand.

Thompson recites a process for making prosthesis for intraluminal implants. (Abstract). The process for making a prosthesis includes the following steps:

> a. providing a plurality of structural strands formed of a structural material and having an original nominal shape, and providing a plurality of compliant textile strands;
>
> b. altering the structural strands to impart to each of the structural strands a selected nominal shape in lieu of the original nominal shape; and
>
> c. after altering, three-dimensionally braiding the strands into an integrated structure of the structural strands and the textile strands. (Col. 2, lns. 40-21.)

The structural strands preferably are monofilaments of metal, e.g. a stainless steel, an alloy including cobalt or an alloy including titanium. (Col. 4, lns, 7-9). Alternatively the monofilaments are polymeric, constructed of materials including PET, polypropylene, PEEK, HDPE, polysulfone, acetyl, PTFE, FEP, polycarbonate urethane, and polyurethane. (Col. 4, lns, 9-12). In either event the preferred textile strands are multifilament polymeric yarns. (Col. 4, lns, 12-14). Suitable materials for the multifilament yarns include PET, polypropylene, polyurethane, polycarbonate urethane, HDPE (high density polyethylene), polyethylene, silicone, PTFE, ePTFE and polyolefin. (Col. 4, lns. 14-17). A latticework of structural strands can be confined within a medial layer, covered by inner and outer layers of textile sheeting. (Col. 14, lns. 16-18)

As such, Thompson discloses a method for making a braided implant. The implant is formed by braiding structural stands, where the stands can be mono or multi filament, being made of metal or polymeric material. Once formed, the lattice of stand can be covered with an inner and outer layer of textile sheeting. However, Thompson fails to disclose a strand having a outer sheath and end cap disposed on the outer sheath thereby encapsulating the strand.

However, to further provide further clarification, claim 1 now recites, *inter alia*, a stent preform for implantation in a body lumen,. The stent preform includes an elongated metallic core having a contact surface and first and second ends. An outer sheath is disposed about the contact surface of the core, where the outer sheath including a therapeutic agent. Caps are disposed on the ends of the outer sheath thereby encapsulating the first and second end of the core.

In light of the foregoing Applicant submits that claim 52 is patentable over Thompson. Claims 55 and 64-66 depend from claim 52, and include all of the elements of their base claim. Accordingly, Applicant submits that these dependent claims are patentable over Thompson at least for the same reasons.

Claims 52, 54 and 56-62 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,521, 284 to Parsons et al. ("Parsons").

Parsons recites a process for impregnating a porous material with a cross-linkable composition. (Abstract). The process includes spacing the porous material concentrically about

a mandrel to define a cavity therebetween to receive the cross-linkable composition, the mandrel comprising one or more openings for communicating the nonreactive gas, the vacuum, or the combination thereof. (Col. 2, lns 69-63).

Mandrel 2 is hollow, is open on end 8, and is closed on end 10. (Col. 4, lns. 60-61). End 8 and end 10 define a passageway with fluid communication therebetween. (Col. 4, lns. 61-63). Mandrel 2 desirably includes openings 12 which permit passage of fluids therethrough. (Col. 4, lns. 63-64). As seen in FIGS. 2 and 4, a cavity 16 for receiving a cross-linkable polymer composition is defined by spacers 4a and 4b, mandrel 2, and porous material 6. (Col. 4, lns. 64-67). As seen in FIGS. 2-4, spacers 4a and 4b may be used to maintain porous material 6 above the outer surface 20 of the mandrel 2, while not permitting contact therewith. (Col. 5, lns. 21-23).

As such, Parsons discloses a system and method for impregnating an implantable porous material with a cross-linkable composition. The system includes a mandrel about which the porous material is positioned, where the mandrel has an open end and a closed end defining a lumen. Spacers are used to maintain the porous material above the outer surface of the mandrel, where a cavity is defined between the outer surface of the mandrel and the inner surface of the porous material. The cross-linkable composition is place in the cavity.

To impregnate the cross-linkable composition into the porous material, the mandrel in pressurized, where a pressurized gas is injected into the lumen. The pressurized gas propagates to the cavity through the openings along the surface of the mandrel. The pressurized gas forces the cross-linkable composition into the porous material.

It is important to note that the mandrel is not a part of the implantable porous material, being simply a tool used in the impregnation of the cross-linkable composition into implantable porous material. Furthermore, the spacers are only used between the inner surface of the implantable porous material and the outer surface of the mandrel to form a sealed cavity therein. The spacers do not cover the ends of the mandrel.

Accordingly, Parsons is unrelated to a stent preform and fails to disclose a stent preform as recited in claim 1. Specifically, Parsons fails to disclose a stent preform for implantation in a

body lumen having an elongated metallic core including a contact surface and first and second ends; an outer sheath disposed about the contact surface of the core, the outer sheath including a therapeutic agent; and caps disposed on the ends of the outer sheath thereby encapsulating the first and second end of the core.

In light of the foregoing Applicant submits that claim 52 is patentable over Parsons. Claims 54 and 56-62 depend from claim 52, and include all of the elements of their base claim. Accordingly, Applicant submits that these dependent claims are patentable over Parsons at least for the same reasons.

35 U.S.C. §103 Claim Rejections

Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Parsons in view of U.S. Patent No. 5,288,711 to Mitchell et al. ("Mitchell"). Claim 55 was rejected under 35 U.S.C. §103(a) as being unpatentable over Parsons in view of U.S. Patent No. 6,491,662 to Liprie et al. ("Liprie"). Claims 63-69 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parsons in view of U.S. Publication No. 2005/261283 to Sukhatme ("Sukhatme").

As previously discussed, claim 52 is submitted to patentable over Parsons. The inclusion of Mitchell, Liprie, or Sukhatme fails to overcome the deficiencies of Parsons. Claims 53, 55, and 63-69 depend from claim 52, and include all of the elements of their base claim. Accordingly, Applicant submits that these dependent claims are patentable at least for the same reasons.

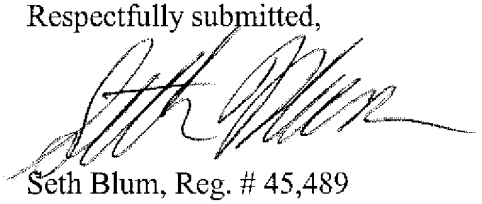
Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed due. However, please charge any l fees (or credit overpayments) to the

Deposit Account of the undersigned, Account No. 503410 (Docket No. 795-A03-004).

Respectfully submitted,



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